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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,249	03/14/2001	Joseph P. Steiner	06843.0036-00000	1312
22852	7590	04/06/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/805,249	<b>Applicant(s)</b> STEINER ET AL.	
	<b>Examiner</b> Vickie Kim	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,7,12-14,25,26,28,29,33,34,36,37,41,42,44 and 45 is/are pending in the application.  
4a) Of the above claim(s) 2-4,6,7,12-14,25,26,28,29,33,34,36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,11,41,42,44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/7, 1/15, 12/30</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Election acknowledged***

1. Applicants' election without traverse of patentably distinct invention of group II, claims 1, 11, 41-42 and 44-45 is acknowledged. Applicants' election with traverse of species, the compound 11(example) is acknowledged. Applicants traversal of the election requirement on the grounds that the species of the genus of formula I is patentably indistinct since the claims that encompass the genus of Formula I has been already issued. However, the argument is not persuasive, as not all invention/species encompassed by the genus would be classified together. For instance, N(nitrogen) containing compound(exclude N containing heterocyclic ring), 5 membered-, 6 membered- or 7 membered heterocyclic(e.g. nitrogen) ring containing compound is classified in 514/579+, 514/ 359+ , 514/ 222.2 +, 514/ 211.01 + , respectively. Furthermore, even if there were unity of classification, the search of the entire genus in the non-patent(a significant part of a thorough examination) would be burdensome. Therefore, the election requirement is maintained, and made FINAL.

### ***Status of Application***

1. Claims 1-4,6,7,12-14,25,26,28,29,33,34,36-37, 41-42, 44-45 are now pending and the elected claims 1,11, 41-42 and 44-45 have been examined only to the extent that they read on use of the elected species in the claimed method. All remaining(or portions thereof) not drawn to the elected species are withdrawn from further consideration as being non-elected.

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2. Applicants informed USPTO that claims 1-48 of this application are believed to correspond substantially to at least claim 2 and/or claim 6 of US6,037,370, issued March 14, 2000, in the name of David M. Armistead. Applicant is requested to file formal request under 37 CFR 1.607 to provoke an interference with said US patent 6,037,370 to Armistead et al.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stimulating neurite outgrowth, does not reasonably provide enablement for treating all possible neurological activities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The treatment of conditions related to neurological activity remains highly unpredictable, and no examples exist for efficacy of a single product against all types of claimed conditions generally. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 1400 (CAFC 1988) at

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1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

- 1) the quality of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working example,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicants fails to provide information allowing the skilled artisan to ascertain “a pathology complicated by neurological activity” without undue experimentation. In the instant case, only a limited number of “a pathology complicated by neurological activity” examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of conditions required. The instant claims read on all “conditions complicated by or associated with neurological activity”, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Therefore, based on the unpredictable nature of the invention and state of the prior art, the lack of guidance and working examples, and the extreme breadth of the

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claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

### ***Allowable Subject Matter***

3. Claims 41-42 and 44-45 are allowed because the claimed subject matter is novel over the prior art of the record.
4. Claims 1 and 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 11, 41-42 and 44-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,11,41-42 and 44-45 of copending Application No. 09/873,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to a method of stimulating neurite outgrowth using FK506 compounds

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having similar structure of general formula, for example, when the substitution of Z position('298) is aryl substituted branched aryl, the scope of each application would be overlapping or close enough to render the claims to be obvious to each other. Since the formula recited in both ('298) and ('249) application undergo same biological pathway(ratamase enzyme inhibition) and share very same pharmacore structure which is responsible for the therapeutic activities, the claimed subject matter is obvious over one to another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

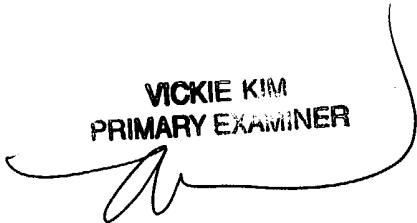
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579(fax: 571-273-0579). The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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**VICKIE KIM**  
**PRIMARY EXAMINER**



Vickie Kim  
April 5, 2004  
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